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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/666,886

09/19/2003

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EXAMINER

BLUMEL, BENJAMIN P

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/666,886	<b>Applicant(s)</b> SEGAL ET AL.	
	<b>Examiner</b> BENJAMIN P. BLUMEL	<b>Art Unit</b> 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 June 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) 4 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 5-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/24/2010</u> .   | 6) <input type="checkbox"/> Other: _____                          |

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### **DETAILED ACTION**

Applicants are informed that Examiner Blumel will be examining the instant application.

Applicants are informed that the rejections of the previous Office action not stated below have been withdrawn from consideration in view of the Applicant's arguments and/or amendments.

### **Continued Examination Under 37 CFR 1.114**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/9/2010 has been entered.

Claims 1-3 and 5-11 are examined on the merits. Claim 4 remains withdrawn as it is drawn to a non-elected species.

### **Information Disclosure Statement**

The information disclosure statement (IDS) submitted on 2/24/2010 was filed after the mailing date of the final Office action on 12/10/2009. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

### **Response to Arguments**

Applicant's arguments filed 6/9/2010 have been fully considered but they are not persuasive. See responses below.

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### **Double Patenting**

In response to the double patenting rejections set forth in the previous office action, and restated below, Applicant submits that upon notification of otherwise allowable subject matter in the instant case, Applicants will address the double patenting rejections.

Applicant's intention is noted. However, until the rejections are properly addressed, with the submission of a terminal disclaimer, all double patenting rejections are maintained for the reason(s) set forth in the record.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Omum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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**(Prior Rejection Maintained)** Claims 1-3 and 5-11 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of copending Application No. 10/666833. The rejection is maintained for reasons of record.

### **Claim Rejections - 35 USC § 112**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**(New Rejection)** Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 8 recites, "...wherein said cell is substantially unable to divide.", however, it is unclear what the metes and bounds of "substantially" are.

### **Claim Rejections - 35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**(New Rejection Necessitated by Amendments)** Claims 1-3 and 5-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoo (US Pat. 5,891,432) and Ramanathan et al. (US PGPub 2003/0091640).

The claims are directed to a composition comprising a virus or cell, and a fusion polypeptide comprising i) a first amino acid sequence that comprises a cell-surface binding moiety and ii) a second amino acid sequence comprising a ligand for a cell surface polypeptide

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of a leukocyte, wherein the virus or cell and the fusion polypeptide are bounded via a lipid on said virus or said cell, and unbounded together. Claim 2, which depends on claim 1, limits the second amino acid sequence to a ligand for a cytokine receptor, which is limited to GM-CSF by claim 3. Claim 5, which depends on claim 1, requires the cell to be a tumor cell, a bacterial cell, a fungal cell, a cell of a parasite, a mammalian cell or an insect cell. Claim 6, which depends on claim 5, requires the cell to be a pathogenic cell. Claim 7, which depends on claim 5, requires the cell to be an attenuated cell. Claim 8, which depends on claim 1, requires the cell to be unable to divide. Claim 9, which depends on claim 1, requires the leukocyte to be an antigen presenting cell, which is specified as a professional antigen presenting cell by claim 10 and dendritic cell by claim 11.

Hoo teaches a composition. [Claims 13-24, in particular.] The composition of Hoo comprises a cell and a fusion polypeptide. [Claims 1-12, in particular.] In the composition of Hoo, the antigen and the fusion polypeptide are bounded and unbounded together. [Claim 1 and claim 12, in particular.] The antigen that Hoo teaches includes a virus, a bacterial cell, fungal cell, a cell of a parasite, a mammalian cell, pathogenic and attenuated antigens, and a cell that is substantially unable to divide. [Lines 35-45, column 10, and columns 9-18, in particular.]

The first amino acid sequence in the fusion polypeptide of Hoo comprises the sequence to a membrane attachment domain, a cell-surface binding moiety. The second amino acid sequence in the fusion polypeptide of Hoo comprises the sequence of a ligand for a cell surface polypeptide of a leukocyte. Specifically, the ligand for a cell surface polypeptide of a leukocyte is a ligand for a cytokine receptor. In particular, the ligand for a cytokine receptor that Hoo et al.

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teaches is GM-CSF. [Example I, column 22, in particular.] The ligand for a cell surface polypeptide used by Hoo is a ligand for a cell surface polypeptide of a leukocyte, wherein the leukocyte is dendritic cells, which is a professional antigen presenting cell. [Columns 1-2, in particular.] In the instant case, the composition of Hoo is the same as the claimed invention. However, Hoo does not teach the binding of the fusion polypeptide via a lipid on the virus or the cell through a cell-surface binding moiety.

Ramanathan et al. teach the development of cell binding moiety that can bind to lipids of a cell. See claims 1 and 22.

It would have been obvious to one of ordinary skill in the art to modify the composition taught by Hoo in order to use a lipid of a virus or cell to bind a fusion polypeptide. One would have been motivated to do so, given the suggestion by Hoo that the cell-binding moieties be used to associate a fusion polypeptide with a membrane of a cell or virus. There would have been a reasonable expectation of success, given the knowledge that cell-binding moieties can be developed to bind lipid on a cell surface, as taught by Ramanathan et al. Thus the invention as a whole was clearly prima facie obvious to one of ordinary skill in the art at the time the invention was made.

**Response to arguments:**

Applicants argue that Hoo does not teach the binding of lipid on a virus or cell with a cell-surface binding moiety.

It is acknowledged that Hoo do not specifically state that a lipid is the target of their cell-surface binding moieties. However, Ramanathan et al. do teach the development of cell binding

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moieties that associate/bind with lipids on cells. Therefore, the instant invention is prima facie obvious to one of ordinary skill in the art at the time the invention was made.

### **Conclusion**

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BENJAMIN P. BLUMEL whose telephone number is (571)272-4960. The examiner can normally be reached on M-F, 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Zachariah Lucas can be reached on 571-272-0905. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/BENJAMIN P BLUMEL/  
Examiner  
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